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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,069	04/04/2001	Yaakov Naparstek	56040-B/JPW/GJG/CSN	3884
7590 09/08/2006				
Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			EXAMINER EWOLDT, GERALD R	
			ART UNIT 1644	PAPER NUMBER
DATE MAILED: 09/08/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/826,069		NAPARSTEK, YAAKOV	
	Examiner		Art Unit	
	G. R. Ewoldt, Ph.D.		1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendment and remarks, filed 7/31/06, are acknowledged.
2. Claims 8-10, and newly added Claims 11-14, are being acted upon.
3. As set forth previously, the priority date of the instant application is its filing date, 4/04/2001.
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 8-10, and newly added Claims 11-14, stand/are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaubitz et al. (1999) in view of U.S. Patent No. 6,228,363 and Madaio et al. (1996).

As set forth previously, Gaubitz, M., et al. teaches a method of treating lupus comprising extracorporeal column immunoadsorption of a subject's plasma for the removal of pathogenic antibodies. The reference further teaches that dsDNA-Ab play a "pivotal" role in the pathogenesis of SLE and that their removal proved useful for the treatment of the disease (see particularly Introduction and Discussion).

The reference teaching differs from the claimed invention only in that it does not teach a method employing a column comprising the R38 peptide nor the use of a Sepharose™ column.

The '363 patent teaches that the R38 peptide is derived from laminin and is recognized by pathogenic lupus antibodies (see particularly column 3, lines 13-19).

Madaio et al. teaches that dsDNA-Ab from lupus patients also recognize laminin (see particularly Abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of treating lupus comprising extracorporeal column immunoadsorption of a subject's plasma for the removal of pathogenic antibodies, as taught by Gaubitz et al., employing the R38 peptide of the '363 patent. One of ordinary skill in the art at the time the

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invention was made would have been motivated to employ the R38 peptide on an immunoabsorption column given the teachings of Madaio et al. that dsDNA-Ab from lupus patients also recognize laminin and the '363 patent that the R38 peptide is derived from laminin and is recognized by pathogenic lupus antibodies. Note that Claim 8 is included in the rejection because various types of immunoabsorber matrices (including Sepharose™) for column chromatography were well-known in the art at the time of the invention. The choice of any particular immunoabsorber matrix would have comprised only routine optimization of the claimed method and would have been well within the purview of one of ordinary skill in the art at the time of the invention. Note that new claim 10 does not recite any new limitations because all ligands are coupled to Sepharose™ in some sort of "coupling buffer" (an ordinarily skilled artisan would know that Sepharose™ could not be used in a dry form for column chromatography because column chromatography employs the flow of liquid through the column).

Applicant's arguments, filed 7/31/06, have been fully considered but they are not persuasive. Applicant argues "... The rejection of record continues to lack an explanation of how the combined disclosure of the cited references teaches every element of a rejected claim."

"Specifically, the combined references fail to teach the element of "extracorporeal treatment of plasma ... by affinity absorption column chromatography, wherein the column comprises a peptide having an amino acid sequence as set forth in SEQ. ID. NO. 1."

Additionally, Applicant again argues against the rejections individually.

Applicant is again reminded that it is the combination of references, in further view of the knowledge of the ordinarily skilled artisan, upon which the rejection is based.

Applicant argues that a proper obviousness rejection must show each and every element of the rejected claims.

The Examiner is well aware of the Examiner's burden regarding a proper showing of obviousness. Applicant is reminded that MPEP 2143.01 states, "Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art". Thus, Applicant seems to have ignored the section regarding, "the knowledge generally available to one of ordinary skill in the art" in the instant rejection. Further note MPEP 2144, "The rationale to modify or combine the prior art does not

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have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law." Thus, the MPEP teaches the use of "logic and sound scientific reasoning".

Applicant argues that laminin and the R38 peptide are not the same, thus, teachings regarding laminin cannot be applied to the R38 peptide.

Applicant is advised that the '363 patent teaches that the R38 peptide is derived from laminin and is recognized by pathogenic lupus antibodies. Thus, its use in the immunoabsorber employed in the claimed method comprises no more than an obvious substitution.

Applicant asserts that the Examiner is advancing an "obvious to try" theory.

As the skilled artisan would expect that a column employing an R38 peptide would bind pathogenic lupus antibodies, Applicant's assertions are not persuasive. See particularly MPEP 2143.02 wherein it is taught that the substitution of compounds with similar activities (like the immunoabsorbers in the instant case that both bind pathogenic antibodies) is obvious.

Applicant asserts that the Examiner is employing improper hindsight.

Regarding the use of hindsight, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

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Applicant argues that the binding of an antibody on a plate in an ELISA offers no expectation of binding in a column. Applicant further asserts that conformational structure and time can affect binding.

As set forth previously, Applicant is again advised that the binding of antibodies to Sepharose™ beads is routine in the art.

Applicant argues that the Examiner has dismissed the Inventor's 132 declaration.

Applicant appears to have confused his own previous arguments and reasons for making said arguments. It was the Examiner's position that the use of an affinity column in the method of the instant claims is not particularly unpredictable as Gaubitz et al. demonstrated a reduction of antibody concentration on the order of 70% employing a column. Applicant then argued unpredictable results and submitted the Inventor's declaration. It was, and still is, the Examiner's position that no unpredictable results were demonstrated and regardless, arguments of unexpected results properly belong in the specification. Assertions of unexpected results employing post-filing experiments are not persuasive.

Applicant argues that the results of Gaubitz et al. cannot be compared to Applicant's results as Gaubitz et al. did not target the anti-R38 antibody.

It is the Examiner's position that no special properties of the anti-R38 antibody have been demonstrated such that results regarding the antibodies of Gaubitz et al. would not be expected to be achievable with the anti-R38 antibody.

Applicant states that no admission of obviousness has been made.

Applicant's statement is noted.

6. The following are new grounds for rejection necessitated by Applicant's amendment.

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7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, A method of treating a subject having systemic lupus erythematosus comprising extracorporeal treatment of plasma from the subject by affinity absorption column chromatography, wherein the column consists essentially of a peptide having an amino acid sequence as set forth in SEQ. ID. NO. 1 and returning plasma so treated to the patient

Applicant cites pages 4 and 11 and Figures 5, 6, 7, and 9 for support.

Page 4 of the specification discloses only that the R38 peptide is recognized by pathogenic antibodies and might therefore be used in a method of treatment. Page 11 and the figures disclose results of specific experiments, indeed the experiment at page 11 employs a mouse model of SLE. Clearly, these cites do not support the broad method of the claim which even encompasses the administration of the R38 peptide to humans

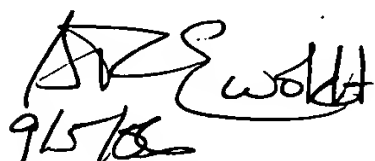
9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

12. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600